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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,730	01/02/2002	Robert M. Abrams	99-0137 (US02)	3733

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,730	ABRAMS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-41,43,44,46,53-57 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-41, 43, 44, 46, 53-57, and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 1/24/06.

Claims 32-41, 43, 44, 46, 53-57, and 59 remain pending and are under consideration in this Office Action.

Drawings

No drawings were filed with the application.

Rejections Withdrawn

The rejection of claims 32-41, 43, 44, 46, 53-57, and 59 under 35 USC 112, first paragraph for new matter is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 33, 38, 39, 53-55, and 59 stand rejected under 35 U.S.C. 102(e) as being anticipated by Evans (US Patent 5,702,361).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18. Both components of the system are considered to be biologically active inasmuch as they cause clot formation. See e.g. column 9, lines 27-33. The particular biocompatible polymer employed is not critical and is selected relative to the viscosity of the resulting polymer solution, the solubility of the biocompatible polymer in the biocompatible solvent, the compatibility of the polymer composition with the non-particulate agent and the like. Such factors are well within the skill of the art. See column 5, lines 34-39. The biocompatible solvent can be an aqueous mixture comprising ethanol. See column 6, lines 44-52.

Evans also taught a method in which the non-particulate agent (e.g., platinum coils) is first introduced to the vascular site to be embolized via conventional catheter technology. After introduction of the non-particulate agent to the vascular site, a sufficient amount of the polymer composition is introduced by conventional means (e.g., catheter delivery under fluoroscopy). See column 8, lines 12-23.

Evans also taught kits comprising:

(a) a polymer composition comprising a biocompatible polymer, a biocompatible solvent and a contrast agent; and

(b) a non-particulate agent or plurality of such agents; or

(a) a prepolymer composition comprising a biocompatible prepolymer and a contrast agent; and

(b) a non-particulate agent or plurality of such agents.

Preferably, in either case, the kit further comprises a catheter capable of delivering said polymer or prepolymer composition.

Thus Evans anticipates the claims.

Response to Arguments

Applicant's arguments filed 1/24/06 have been fully considered but they are not persuasive. Applicant argues at pages 7 and 8 of the response that Evans fails to teach a biologically active component, noting that the instant specification indicates that this component is "preferably a medicine or angiogenic material", and that the specification sets forth non-limiting examples of bioactive material. This is unpersuasive because it requires an unduly narrow interpretation of "biologically active material". The polymer of Evans is considered to be biologically active clot formation is a biological process, and the polymer of Evans clot formation. See e.g. column 9, lines 27-33. For this reason the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32 and 34-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent 5,702,361) in view of Slepian (US Patent 5,634,946).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18. The particular biocompatible polymer employed is not critical and is selected relative to the viscosity of the resulting polymer solution, the solubility of the biocompatible polymer in the biocompatible solvent, the

compatibility of the polymer composition with the non-particulate agent and the like. Such factors are well within the skill of the art. See column 5, lines 34-39.

Evans did not teach the use of polyesters or polyhydroxybutyrate as a biocompatible polymer.

Slepian taught a method for forming a biocompatible polymer coating on a tissue surface of a lumen in a body vessel, wherein the polymer is a biocompatible polymer selected from the group consisting of polymers and copolymers of hydroxycarboxylic acids, polyurethanes, polyesters, polyamides, polyacrylonitriles, polyphosphazenes, polylactones, polyanhydrides, polyethylenes, polyalkysulfones, polycarbonates, polyhydroxybutyrates, polyhydroxyvalerates, hydrocarbon polymers, polypropylenes polyvinylchlorides, ethylene vinyl acetates and combinations thereof. See claim 5. Slepian also taught that the polymers could be used to occlude a tissue lumen completely. See paragraph bridging columns 8 and 9.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the polymers of Slepian in the method of Evans because these are considered to be recognized equivalents in the art of tissue lumen occlusion, and the invention of Evans is directed to occlusion of the lumens of blood vessels. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07

indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Thus the invention as a whole was prima facie obvious.

Claims 32, 40, 41, 43, 44, and 46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent 5,702,361) in view of Murayama et al (US Patent 5,891,192).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18.

Evans did not teach a biologically active component that are not the embolizing polymer, such as components that increase cell attachment or thrombogenicity.

Murayama taught that coating intralumenal coils led to improved performance by controlling thrombosis and increasing re-endothelialization and cell adhesion. See e.g.

column 1, lines 57-67; column 2, line 64 to column 3, line 8; and paragraph bridging columns 5 and 6.

It would have been obvious to one of ordinary skill in the art to coat the coils of Evans with fibronectin, as taught by Murayama in order to obtain the improved performance taught by Murayama.

Thus the invention as a whole was prima facie obvious.

Claims 32, 40, 41, 43, 44, and 46, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent 5,702,361) in view of Murayama et al (US Patent 5,891,192).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18.

Evans did not teach a biologically active component that is not the embolizing polymer, such as a component that increases cell attachment or thrombogenicity.

Murayama taught that coating intralumenal coils led to improved performance by controlling thrombosis and increasing re-endothelialization and cell adhesion. See e.g. column 1, lines 57-67; column 2, line 64 to column 3, line 8; and paragraph bridging columns 5 and 6.

It would have been obvious to one of ordinary skill in the art to include in the polymer-forming composition of Evans the fibronectin of Murayama. One would have been motivated to do so in order to obtain the advantages of Murayama in the embolism forming composition.

Thus the invention as a whole was prima facie obvious.

Response to Arguments

Applicant's arguments filed 1/24/06 have been fully considered but they are not persuasive.

Applicant addresses the rejection over Evans and Slepian at pages 8 and 9 of the response, and the rejection over Evans and Murayama at page 10 of the response. Applicant argues that Evans fails to teach a biologically active agent. This is unpersuasive for the reasons set forth above, i.e. the polymer of Evans is considered to be biologically active clot formation is a biological process, and the polymer of Evans clot formation. See e.g. column 9, lines 27-33. Applicant also argues that there is no reasonable expectation of success, in either combination stating that one of skill in the art would not have expected success if he removed the non-particulate element of Evan's invention. This is unpersuasive because the rejections do not require that one

remove the non-particulate element (i.e. the metal coil) from the invention of Evans. In fact, the rejection requires the opposite, that one retain the non-particulate element, because it corresponds to the mechanical occlusive device of the instant invention.

For these reasons the rejections are maintained.

Conclusion

No claim is allowed. Claims 37, 56, and 57 are objected to because they depend from a rejected claims(s), but would be allowable if rewritten in independent form incorporating all of the limitations of the claim(s) from which they depend.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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